K121959

510(k) SUMMARY
EVIS EXERA III VIDEO SYSTEM

JAN 10 2013

ENDOSCOPIC VIDEO IMAGING SYSTEM

January 8, 2013

1 General Information

- Applicant:

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo, Japan 192-8507
Establishment Registration No: 8010047

- Official Correspondent:

Laura Storms-Tyler
Regulatory Affairs & Quality Assurance
Olympus America Inc.
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610, USA
Phone: 484-896-5688
FAX: 484-896-7128
Email: laura.storms-tyler@olympus.com

- Manufacturer:

(Endoscopes)
Aizu Olympus Co., Ltd.
500 Aza-Muranishi, Ooaza-Iidera, Monden-cho,
Aizuwakamatsu-shi, Fukushima, Japan 965-8520
Establishment Registration No.: 9610595

(CV-190, CLV-190)
SHIRAKAWA OLYMPUS CO., LTD.3-1,
Aza-Ookamiyama, Ooaza-Odakura, Nishigo-mura,
Nishishirakawa-gun, Fukushima, Japan 961-8061
Establishment Registration No: 3002808148

2 Device Identification

- Device Trade Name: EVIS EXERA III VIDEO SYSTEM
- Common Name: ENDOSCOPIC VIDEO IMAGING SYSTEM
- Regulation Number: 874.4680
  876.1500
- Regulation Name: Bronchoscope (flexible or rigid) and accessories
  Endoscope and Accessories
- Regulatory Class: II

- Classification Panel: Ear, Nose and Throat
- Product Code: EOQ and NWB

3 Predicate Device Information

Subject Device (Part of this submission)	Predicate Device	PD's 510(k) No.	Manufacturer
OLYMPUS BF-Q190 EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-H190 EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-1TH190 EVIS EXERA III BRONCHOVIDEOSCOPE	EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE P180, EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE Q180, EVIS EXERA II BRONCHOVIDEOSCOPE OLYMPUS BF TYPE 1T180	K061313	Aizu Olympus Co., Ltd.
OLYMPUS CLV-190 EVIS EXERA III XENON LIGHT SOURCE	EVIS EXERA Xenon Light Source OLYMPUS CLV-160A	K051645	SHIRAKAWA OLYMPUS CO., LTD. 3-1,
	EVIS EXERA II XENON LIGHT SOURCE OLYMPUS CLV-180	K061313 K062049 K100584	
OLYMPUS CV-190 EVIS EXERA III VIDEO SYSTEM CENTER	EVIS EXERA Video System Center OLYMPUS CV-160A	K051645	
	EVIS EXERA II VIDEO SYSTEM CENTER OLYMPUS CV-180	K061313 K062049 K100584	

4 Device Description

The EVIS EXERA III VIDEO SYSTEM consists of Olympus camera heads, endoscopes, video system center, light source, monitors, EndoTherapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

The primary components of the subject system, which are part of this submission, are:
- Video System Center OLYMPUS CV-190
- XENON LIGHT SOURCE OLYMPUS CLV-190
- BRONCHOVIDEOSCOPE OLYMPUS BF-Q190, BF-H190, BF-1TH190

The CV-190 contains the video signal processing technology which enables the endoscope to

illuminate, enhance, view, record and transmit video data of endoscopic images. The OLYMPUS CV-190 allows image display on HDTV (16:9).

The XENON LIGHT SOURCE OLYMPUS CLV-190 is intended for endoscopic diagnosis, treatment and video observation.

In addition, both the CV-190 and CLV-190 can be used with any specified Olympus flexible and rigid endoscope models, including gastroscopes, ultrasound gastroscopes, duodenoscopes, colonoscopes, sigmoidscopes, choledochoscopes, bronchoscopes, rhino-laryngoscopes, tracheal intubation scopes, transnasal esophago scopes, hysteroscopes, cystoscopes, ureterorenoscopes, laparo-thoracoscopes.

The subject endoscopes are intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment.

5 Indications for Use

- Endoscopes (OLYMPUS BF-Q190, OLYMPUS BF-H190, OLYMPUS BF-1TH190 EVIS EXERA III BRONCHOVIDEOSCOPE)

This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. This instrument is indicated for use within the airways and tracheobronchial tree.

- OLYMPUS CV-190 EVIS EXERA III VIDEO SYSTEM CENTER

This video system center is intended to be used with Olympus camera heads, endoscopes, light source, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

- OLYMPUS CLV-190 EVIS EXERA III XENON LIGHT SOURCE

This light source is intended to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

6 Comparison of Technological Characteristics

The CV-190 incorporates the following features that are different from the compared predicate device: (1) Provides high quality endoscopic image by using the subject device with new endoscopes and light sources, (2) Noise reduction, (3) Color correction, (4) Pre-freeze, (5) Brighter and more contrasted NBI observation, (6) Ethernet interface.

The CLV-190 incorporates the following features compared to the predicate device: (1) User friendly new connector, (2) Built-in type power fuse, (3) High-definition images, (4) IR absorbing filter removed.

The endoscopes contains the following features compared to the predicate device: (1) Light-guide

and electronic-contact Integrated connector (2) Insertion tube rotation function (3) Wider angulation range (4) Improved image quality (as a result of a new CCD)

7 Summary of non-clinical testing

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. The design verifications tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

Reprocessing validation was carried out in accordance with "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance - April 1996."

The software validation activities were performed in accordance with the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The device software is considered a "Minor Level of Concern."

The following standards have been applied to the EVIS EXERA II VIDEO SYSTEM:

- IEC 60601-1
- IEC 60601-1-1
- IEC 60601-2-18
- IEC 60601-1-2
- ISO 14971
- ASTM E1837-96
- ANSI/AAMI/ISO 11135-1
- ISO 10993-1
- ISO 10993-5
- ISO 10993-10

8 Conclusion

When compared to the predicate device, the EVIS EXERA III VIDEO SYSTEM does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 10, 2013

Laura Storms-Tyler
Executive Vice President RA/QA
Olympus America, Inc.
3500 Corporate Parkway
PO Box 610
Center Valley, PA 18034-0610

Re: K121959
Trade Name: Evis Exera III Video System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOQ, NWB
Dated: November 30, 2012
Received: December 3, 2012

Dear Ms. Storms-Tyler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K121959

Indications for Use

510(k) Number (if known): K121959
Device Name: EVIS EXERA III 190 SYSTEM

Indications For Use:

- Endoscopes (OLYMPUS BF-Q190, OLYMPUS BF-H190, OLYMPUS BF-1TH190 EVIS EXERA III BRONCHOVIDEOSCOPE)
This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery. This instrument is indicated for use within the airways and tracheobronchial tree.

- OLYMPUS CV-190 EVIS EXERA III VIDEO SYSTEM CENTER
This video system center is intended to be used with Olympus camera heads, endoscopes, light source, monitors, endo-therapy accessories and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

- OLYMPUS CLV-190 EVIS EXERA III XENON LIGHT SOURCE
This light source is intended to be used with Olympus endoscopes, video system center, and other ancillary equipment for endoscopic diagnosis, treatment and video observation.

Prescription Use ✓ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Neurological and Physical Medicine Devices
510(k) Number K121959